



SEP 28 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Ammar Al-Dojally  
Engineering Manager  
O-Two Medical Technologies, Incorporated  
7575 Kimbel Street  
Mississauga, Ontario,  
CANADA L5S 1C8

Re: K051469  
Trade/Device Name: CAREvent ATV + CAREvent MRI  
Regulation Number: 21 CFR 868.5925  
Regulation Name: Powered Emergency Ventilator  
Regulatory Class: II  
Product Code: BTL  
Dated: September 19, 2005  
Received: September 22, 2005

Dear Mr. Al-Dojally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a large, stylized loop at the beginning.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K051469

Device Name: CAREvent ATV+ and CAREvent MRI

### Indications For Use:

The CAREvent ATV+ and CAREvent MRI are pneumatically powered, time cycled, intermittent, positive pressure automatic transport ventilator used to provide resuscitation and/or ventilatory support to a wide range of patients (from above 5 kg (11 lbs.) and higher) during transport.

They are designed to be used by suitably trained medical personnel in the pre-hospital, Intra-hospital, inter-hospital and air ambulance settings.

In addition CAREvent MRI is suitable for use in 1.5 - 3.0 Tesla MRI medical imaging suite environments, where ventilatory support may also be required during an MRI imaging procedure.

The ventilator is suitable for use in:

- Pulmonary resuscitation during respiratory and/or cardiac arrest.
- Short term ventilatory support in the pre-hospital, Intra-hospital, inter-hospital and air ambulance transport of non-breathing patients.
- In addition CAREvent MRI only is suitable for use in 1.5 - 3.0 Tesla MRI medical imaging suite environments, where ventilatory support may also be required during an MRI imaging procedure.


Prescription Use ☒   
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐   
 (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K 051469